

EXPRESS MAILING NO.:

EL615211957US



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OCT 08 2002

TECH CENTER 1600/2900

FORM PTO-1083

Attorney Docket No.00800.0051.CNUS03

Box:

THE COMMISSIONER FOR PATENTS  
 Washington, D.C. 20231

Sir:

In re application of: Emil D. KAKKIS

Application Serial No. 09/993,241

Filed: November 13, 2001

For: METHODS FOR TREATING DISEASES CAUSED BY DEFICIENCIES OF RECOMBINANT  $\alpha$ -L-  
 IDURONIDASE

Transmitted herewith are the following:

1. PTO Form 1083;
2. Preliminary Amendment;
3. Clean Version with Amendments Incorporated;
4. Marked-up Version to Show Changes Made;
5. Check in the amount of \$321.00; and
6. Return receipt postcard.

\_\_\_ No Additional Claim Fee is required.

The claim fee has been calculated as shown below:

	(Col. 1)		(Col. 2)	(Col. 3)
	Claims Remaining After Amendment		Highest No. Previously Paid For	Present Extra
Total Claims	57	MINUS	26	= 31
Indep. Claims	4	MINUS	3	= 1
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				

## SMALL ENTITY

Rate	Addit. Fee
x 9 =	\$ 279.00
X 42 =	\$ 42.00
+135 =	\$ .00
Total Addit. Fee	\$ 321.00

Or

OTHER THAN A  
SMALL ENTITY

Rate	Addit. Fee
x 18 =	\$ 00.00
x 84 =	\$ 00.00
+ 270 =	\$ 00.00
TOTAL	\$ 00.00

Or

xx The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 08-3038 referencing Attorney Docket No.: 00800.0051.00US00.

Date: October 2, 2002

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re application of: Emil D. KAKKIS

Application No.: 09/993,241

Filed: November 13, 2001

For: **METHODS FOR TREATING DISEASES  
CAUSED BY DEFICIENCIES OF  
RECOMBINANT  $\alpha$ -L-IDURONIDASE**

Art Unit: 1652

Examiner: Not yet assigned

Attorney Docket No: 00800.0051.CNUS03

TECH CENTER 1600/2900

9/B  
S.G.J  
10/15/02

**PRELIMINARY AMENDMENT**

Director of the U.S. Patent and Trademark Office  
Washington, D.C. 20231

Sir:

**AMENDMENT**

**In the Claims:**

Claims 19, 21, 22, 24, 26 and 28 as amended follows:.

B1 19. (Amended) The method of Claim 14 wherein the disease is  
mucopolysaccharidosis I.

21. (Amended) The method of Claim 14 wherein said human subject suffering from  
the disease demonstrates about 1% or less of a normal  $\alpha$ -L-iduronidase activity.

B2 22. (Amended) The method of Claim 14 wherein a dose of at least about 100 units  
per kilogram said human recombinant  $\alpha$ -L-iduronidase is administered weekly to said human  
subject suffering from said deficiency.

B3 24. (Amended) The method of Claim 14 wherein said administering is a slow  
infusion of at least 0.5 mg/kg of said formulation for about an hour, followed by a rapid two-hour  
infusion rate.

10/07/2002 SMITHASS1 00000067 09993241  
279.00 OP  
42.00 OP  
01 FC:203  
02 FC:202